IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Aaron W. Janke et al.	Examiner: George Evanisko
Serial No.:	10/650,207	Group Art Unit: 3762
Filed:	August 28, 2003	Docket No.: 279.093US3
Customer No.: 45458		Confirmation No.: 9733
Title:	HIGH IMPEDANCE ELECTRODE TIP	

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. § 41.41

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In response to the Examiner's Answer mailed August 6, 2009, please see the remarks below:

REMARKS

Appellant has reviewed the Examiner's Answer, and believes the statements in the Appeal Brief remain accurate and compelling. In responding to the Answer, the Appellant would like to further explore a selected few of the points raised by the Office.

§103 Rejection of the Claims

Discussion of the rejection of claims 1-5, 7, and 8, and 16-19 under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074) in view of Dutcher et al. (U.S. Patent No. 5,217,028); and discussion of the rejection of claims 1, 2, 3, 7, 8 and 16-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Claim 1 recites: a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient.

It is Appellant's position that the Dutcher reference does not include or suggest such subject matter. In the Examiner's Answer, the Examiner states "Dutcher discloses a plastic/polyurethane drug plug, 138 (e.g. col. 4, line 57), that coats/conforms to the helix (figure 5). Plastic/polyurethane is an insulating material and figure 5 clearly shows the drug plug covering/conforming/coating the helix." (Page 17 of Examiner's Answer).

Appellant traverses this characterization of the Dutcher reference. Drug plug 138 does not conform to the outer surface of the helix. In contrast, the plug 138 is merely held within the rear inner area of the helix. The plug 138 itself does not conform to or coat the helix outer surface. Moreover, as described in the Dutcher reference: "The drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 is positioned in contacting relationship with the heart tissue." (Col. 4, lines 53-56). Accordingly, even during use, the plug 138 in no way conforms to or coats the helix outer surface.

As an alternative, the Examiner's Answer continues that "Dutcher also discloses the use

of another insulation layer, 133 (e.g. col. 3, line 58), coating the helix that contacts drug plug, 138 (e.g. figure 5). The connection/contacting of insulation, 133, and drug plug, 138, provides the claimed insulation material "including" an active ingredient since "including" does not necessarily mean that the insulation material incorporates the active ingredient directly into the material, but just that the insulation has an active ingredient. Since the drug plug, 138, is located on the insulation, 133, and/or since the drug will migrate on the insulation, the insulation will "include" the active ingredient." (Page 17 of Examiner's Answer).

Appellant again traverses this characterization of the Dutcher reference. The insulation 133 of Dutcher does not have an active ingredient. Merely because the drug plug 138 is proximate the insulation 133 does not permit a characterization that the insulation 133 includes an active ingredient. Also, as noted above, the Dutcher reference describes that: "The drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 is positioned in contacting relationship with the heart tissue." (Col. 4, lines 53-56). Thus, the Dutcher reference itself does not state that the drug is included or contained in or will even travel along the insulative coating 133.

Independent claim 16 includes a similar limitation as discussed above and the discussion above for claim 1 is incorporated herein by reference.

Discussion of the rejection of claims 1-5, 7, and 8 and 16-19 under 35 U.S.C. §103(a) as being unpatentable over Bisping (U.S. Patent No. 4,886,074) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Appellant believes claim claims 1-5, 7, and 8 and 16-19 are not obvious in view of the cited references since there is no reason or suggestion to combine the references.

Here, Altman discusses different coatings for an implantable device which is for "effective elimination of an arrhythmogenic site." (Abstract). In contrast, Bisping relates to an implantable electrode type lead assembly. (Abstract). Thus, there appears to be no motivation or reason to apply any of Altman's or Hoffman's discussions to the lead of Bisping, since they are used for generally different purposes.

The Examiner's Answer again states that "Altman is in the same field of endeavor as Bisping, i.e. fixation helixes used to screw into the heart." (Page 18 of Examiner's Answer).

However, Bisping gives no indication of a need for any of the Objects of Invention described in Altman at col. 6, line 20 – col. 7 line 3, where the Altman disclosure discusses different purposes of the device to treat arrythmogenic sites. Merely because Altman discusses a helix shape for the arrythmogenic treatment device does not mean that his disclosure applies to a helix used for a completely different purpose, such as the Bisping helix, which is used as a fixation device to hold an electrode in place.

Regarding the Hoffman reference, the Hoffman reference discusses a lead having a hydrogel coating. (Abstract). It discusses nothing of an insulative coating for a helix. The Hoffman reference teaches away from such an application of the hydrogel coating. For instance, at col. 6, lines 7-12, Hoffman states that "It is not necessary to apply the hydrogel to the connectors, the pacing tip electrode, or the region of the lead that will be coiled into the subcutaneous area. If the pacing tip electrode were coated, tissue would not grow into the pores, thereby not providing firm stabilization of the lead at the tip."

Discussion of the rejection of claims 1, 2, 3, 7, and 8 and 16-19 under 35 U.S.C. § 103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Appellant believes claim 1, 2, 3, 7, and 8 and 16-19 are not obvious in view of the cited references since there is no reason or suggestion to combine the references.

Again, Altman discusses different coatings for an implantable device which is for "effective elimination of an arrhythmogenic site." (Abstract). In contrast, Grassi relates to an implantable electrode for a pacemaker. (Abstract). Thus, there appears to be no motivation or reason to apply any of Altman's discussion to the lead of Grassi, since they are used for generally different purposes. The Grassi disclosure gives no indication of a need for any of the Objects of Invention described in Altman at col. 6, line 20 – col. 7 line 3, where the Altman disclosure discusses different purposes of the device to treat arrythmogenic sites. Merely because Altman discusses a helix shape for the arrythmogenic treatment device does not mean

that the disclosure applies to a helix used for a completely different purpose, such as the Grassi helix, which is used as a fixation device to hold an electrode in place.

Regarding the Hoffman reference, the Hoffman reference discusses a lead having a hydrogel coating. (Abstract). It discusses nothing of an insulative coating for a helix. The Hoffman reference teaches away from such an application of the hydrogel coating. For instance, at col. 6, lines 7-12, Hoffman states that "It is not necessary to apply the hydrogel to the connectors, the pacing tip electrode, or the region of the lead that will be coiled into the subcutaneous area. If the pacing tip electrode were coated, tissue would not grow into the pores, thereby not providing firm stabilization of the lead at the tip."

CONCLUSION

Appellants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Appellants' representative at (612) 359-3267 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account 19-0743.

Respectfully submitted,

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Date October 6, 2009

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 6th day of October, 2009.

Kate Gannon — / Kate Gannon /

Name — Signature